

510(k) Summary

Submitted By:

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NOV 09 2007

Device:

Trade Name: Cxi Support Catheter
Proposed Classification: Catheter, Continuous Flush
KRA (21 CFR §870.1250)

Indications for Use:

Intended for use in small vessel or superselective anatomy for diagnostic and interventional procedures including peripheral use.

Predicate Devices:

The Cxi Support Catheter is similar in terms of intended use, principles of operation, materials of construction and technological characteristics to predicate devices reviewed as devices for use in small vessel or superselective anatomy for diagnostic and interventional procedures.

Device Description:

The Cxi Support Catheter consists of a 2.6 French catheter with hydrophilic coating. The catheter includes four (4) radiopaque markers to assist in fluoroscopic visualization of the catheter during use. The inner diameter allows acceptance of a 0.018-inch (0.45mm) wire guide. The catheter is available in two lengths, 90 and 150 cm, with a straight or angled distal tip.

Substantial Equivalence:

The Cxi Support Catheter is similar to catheters in commercial distribution for use in small vessel or superselective anatomy for diagnostics and interventional procedures. The device most similar is the MiraFlex 18 Microcatheter cleared for marketing on December 8, 2005 (D.C.#K052841) and March 6, 2006 (D.C.#K060224).

The similar indications for use, principles of operation, technological characteristics and performance testing results for the Cxi Support Catheter as compared to the predicate device supports a determination of substantial equivalency.

Test Data:

The Cxi Support Catheter was subjected to the following tests to assure reliable design and performance under specified testing parameters. These tests were comprised of:

1. Freedom of Leakage
2. Burst Pressure
3. Tensile Strength
4. Bending
5. Flow Rate
6. Biocompatibility

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its use as a catheter guide wire.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 09 2007

Cook Inc.
c/o Ms. Karen Bradburn
Senior Regulatory Affairs Specialist
P.O. Box 489
Bloomington, IN 47402-0489

Re: K072724
CXI Support Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: II (Two)
Product Code: KRA
Dated: October 31, 2007
Received: November 1, 2007

Dear Ms. Bradburn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Anna R. Vuchner

 Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K072724

Device Name: Cxi Support Catheter

Indications for Use: Intended for use in small vessel or superselective anatomy for diagnostic and interventional procedures including peripheral use.

Prescription Use X
(Per 21 CFR 801 Subpart D)

OR

Over-the-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Bohning
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K072724